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Guidance for the Reregistration of Pesticide Products Containing Methoxychlor as the Active Ingredient

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Pesticides

Guidance for the Reregistration of Pesticide Products Containing METHOXYCHLOR as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
METHOXYCHLOR
AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 72-43-5

OPP Chemical Code 034001

EPA CASE NUMBER 0249

December, 1988

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI; Acceptable Daily Intake

a.i.: active ingredient

CAS: Chemical Abstract Services (number)

CSF: Confidential Statement of Formula

EEC: Estimated Environmental Concentration

EPA: The U.S. Environmental Protection Agency (Agency)

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

LC_{50}: Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).

LD_{50}: Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of test animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

LEL: Lowest Effect Level

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number) - EPA's system of tracking studies used in support of registration.

NPDES: National Pollutant Discharge Elimination System

NOEL: No Observed Effect Level

OPP: The Office of Pesticide Programs of the U.S. EPA

PHI: Preharvest Interval

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and the EPA Use Index may be obtained from the National Technical Information Service (NTIS) as of April 1, 1988.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

I. INTRODUCTION

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard:

Common Name: Methoxychlor

Generic (Chemical) Name: 1,1,1-trichloro-2,2-bis(4-methoxyphenyl) ethane

Chemical Family: Chlorinated hydrocarbon

Trade Names: Marlate, Prentox, and Methoxcide

Other Chemical Nomenclature: 1,1,1-trichloro-2,2-di(4-methoxyphenyl)ethane; 1,1-(2,2,2-tri chloroethylidene)bis[4-methoxybenzene]; 1,1,1-trichloro-2,2-bis(p-methoxyphenyl)ethane; 2,2-bis)p-methoxyphenyl)-1,1,1-trichloroethane

CAS Registry No.: 72-43-5

EPA Pesticide Chemical Code (Shaughnessy Number): 034001

Empirical Formula: $C_{16}H_{15}Cl_3O_2$

Molecular Weight: 345.7

Chemical/Physical Characteristics:

Color: Data Gap
Physical State: Crystalline solid (Farm Chemicals, 1987)
Odor: Data Gap
Melting Point: 89 ^{o}C (Farm Chemicals, 1987)
Specific Gravity: Data Gap
Solubility: Very soluble in aromatic chlorinated, or ketonic solvents, somewhat soluble in paraffinic types; essentially insoluble in water (Farm Chemicals, 1987)
Vapor Pressure: Data Gap
Flammability: Data Gap
pH: Data Gap

B. Use Profile

Type of Pesticide: Insecticide/Acaricide

Year of Initial Registration: 1948

Registered Uses:

TERRESTRIAL FOOD CROP: **seed treatment only use** on barley, cotton, flax, lentils, lespedeza, millet, mustard, oats, okra, onion, rape, rice, rye, safflower, sesame, small seed legumes, sorghum, sugar beet, sunflower, swiss chard, trefoil, and wheat; **foliar application (including seed treatment) use** on alfalfa, beans, beets, blueberry, broccoli, brussels sprouts, cabbage, carrots, cauliflower, clover, collards, corn (field and sweet), cowpeas, cucumber, eggplant, endive, grass, kale, kohlrabi, lentils, lettuce, lima beans, melons, peanuts, peas, peppers, potatoes, prune, pumpkin, radish, soybean, spinach, squash, tomato, turnips, and watermelon; **foliar application only use** on apple, apricot, blackberry, asparagus, blackeyed peas, boysenberry, cantaloupe, celery, cherry, currant, dewberry, gooseberry, grapes, loganberry, nectarine, parsnip, peach, pear, pineapple, plum, prune, quince, raspberry, rutabaga, strawberry, sweet potatoes, vetch (grown for seed), yams and youngberry

TERRESTRIAL NON-FOOD CROP: bluegrass (seed treatment), bromegrass, orchardgrass, timothygrass, conifers, elm, hawthorn, ornamental bulb plants, ornamental lawns, ornamental herbaceous plants, ornamental shade trees, ornamental woody shrubs and ornamental vines

GREENHOUSE FOOD CROP: mushrooms

DOMESTIC AND NON-DOMESTIC OUTDOOR: garbage containers, garbage dumps, outdoor domestic dwellings, recreational areas, urban and rural areas, sewage disposal areas and sewer manholes

AQUATIC FOOD: cranberry

AQUATIC NON-FOOD: beaches, estuaries, intermittently flooded areas, lakes, marshes, ponds, sloughs, streams, swamps, temporary rain pools, irrigation canals, woodland pools, rivers and shorelines

FORESTRY: forest trees

INDOOR: **postharvest stored grain commodity and premise treatment** for barley, corn, oats, rye and wheat; **direct animal treatment** for dogs, cats, beef cattle, dairy cattle, goats, guinea pigs, hogs, horses, ponies, poultry, and sheep; **agricultural premise** use for barns (including dairy barns), milk rooms, pens, sheds, stalls, poultry houses, stables, feed rooms and manure piles, **kennels, dog sleeping quarters and cat sleeping quarters; indoor domestic dwellings** for use on household contents such as human clothing (including woolens); **direct application to humans; commercial and industrial** use for food processing plants (edible and inedible) and food processing storage areas (including cereal processing mills, cereal storage areas and flour mills), mausoleums, mushroom house and equipment treatment, transportation vehicles and empty peanut warehouses

Pests Controlled:	various nuisance species (some of public health significance) including cockroaches, mosquitoes, flies and chiggers; various arthropods attacking field crops, vegetables, fruits, ornamentals, stored grain, livestock and domestic pets
Methods of Application:	sprays, fogs, paints, ground and aerial equipment, animal dust-bags, dips, sprays and back-rubbers
Formulations:	wettable powders, dusts, emulsifiable concentrates, flowable concentrates, liquid soluble concentrates, granules, ready-to-use products (liquids) and pressurized liquids
Annual Usage:	500,000 - 900,000 lbs ai (1986 estimate)
Predominant Usage:	alfalfa, livestock, home orchards and ornamentals are the high volume use sites, accounting for approximately 5.4%, 8.9%, 11.5%, and 11.5%, respectively, of the total U.S.

annual usage

Mode of Activity: disrupts nervous system function

U.S. Registrants: Chemical Formulators; Prentiss Drug & Chemical Co., J.R. Simplot Co.; Dynachem Industries; Clover Chemical Co.; Drexel Chemical Co.; Kincaid Enterprises; and Wesley Industries

Number of Registrations: 438 federally-registered end-use products (EPs), 9 technical products, 13 formulation intermediates, and 20 "special local need" registrations issued under FIFRA section 24(c).

C. Data Call-In Notices Issued

The Agency has issued the following 3(c)(2)(B) Data Call-In (DCI) Notices:

Date Issued	Data Required	Status
5/23/84	Teratogenicity-1 species	submitted data determined to be unacceptable
5/28/86	Product Chemistry and Residue Chemistry	submitted data determined to be unacceptable[2]

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[2] Data on fumigated commodities are not required, since there are no registered use patterns. Data on irrigated crop and food handling are required.

III. AGENCY FINDINGS

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of methoxychlor as of November, 1987. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D.

1. With the exception of one mutagenicity study, there are no acceptable acute, subchronic, or long-term toxicology/oncogenicity studies available to support technical methoxychlor. In the acceptable mutagenicity study, an unscheduled DNA synthesis assay in mammalian cells in culture, no abnormal DNA synthesis was noted at any of the dose levels tested.

2. Based on acceptable laboratory data, technical methoxychlor is characterized as very highly toxic to fish and aquatic invertebrates, and practically nontoxic to birds and bees. Based on theoretical calculations, both terrestrial and aquatic uses of methoxychlor may pose a hazard to aquatic organisms, although there is no field evidence to support this. The impacts of methoxychlor use to nontarget organisms will be assessed upon receipt of ecological effects and environmental fate data.

3. The Agency cannot assess the potential for methoxychlor to contaminate groundwater because acceptable environmental fate studies are lacking. Preliminary data suggest that methoxychlor is unlikely to contaminate groundwater because of its low solubility and high rate of adsorption to soil particles. However, environmental fate data are needed in order for the Agency to assess the fate of methoxychlor in the environment and its potential for contaminating groundwater.

4. The nature of the residues of methoxychlor in plants and animals is not adequately understood. None of the tolerances for methoxychlor is adequately supported. Plant and animal metabolism studies, residue studies, analytical methodology, processing studies, and storage stability data are needed before the Agency can determine the adequacy of current tolerance levels.

5. The Preliminary Limiting Dose (PLD)[3] of methoxychlor is .005 mg/kg/day. This is based on a rabbit teratology study with a No Observed Effect Level (NOEL) of 5 mg/kg/day for increased loss of litters and an uncertainty factor of 1000 to account for inter- and intraspecies differences, poor quality of the study used and total lack of the subchronic and chronic toxicity data base. A comparison of the TMRC with the ADI is not appropriate at this time due to the incompleteness of the toxicology and residue chemistry data bases.

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[3] A limiting dose is set when the available data are insufficient to establish an ADI or PADI. Examples of when a limiting dose is used include (1) the use of studies did not demonstrate a NOEL, but rather a minimal effect at the lowest dose; (2) the use of studies which can not be fully evaluated, such as studies in the open literature; and (3) the use of studies which otherwise do not fulfill toxicity data requirements (e.g. subchronic studies of less than 90 days, inhalation or dermal studies which do not allow a conclusive determination of actual dosing)

B. HEALTH EFFECTS ASSESSMENT

With the exception of one mutagenicity study, there are no acceptable acute, subchronic or long-term toxicology studies available to support registration of products containing methoxychlor. Data are required as set forth in Table A of this document.

In the mutagenicity study, a mammalian cell in culture unscheduled DNA synthesis assay (UDS assay), no increase in abnormal DNA synthesis was noted.

C. ENVIRONMENTAL CHARACTERISTICS AND EFFECTS

1. Ecological Effects

Based on acceptable laboratory data, technical methoxychlor is characterized as practically nontoxic to birds on both an acute oral and subacute dietary basis. The single oral dose toxicity (LD_{50}) value to bobwhite was reported to be >2510 mg/kg. The subacute dietary LC_{50} value for this upland gamebird was reported to be >5620 ppm. No data are available on the reproductive effects to birds. An avian reproduction study is required. Depending upon the results of this study and the required environmental fate studies, terrestrial field studies may be required. Terrestrial field studies are not required at this time, since based on theoretical calculations, avian hazards in the field are unlikely. The maximum expected residues of methoxychlor on crops following a single application are calculated to be from 540 to 2230 ppm; LC_{50} values for bobwhite are greater then 5000 ppm. Therefore, hazards to terrestrial organisms are unlikely.

Based on acceptable laboratory data, technical methoxychlor is characterized as very highly toxic to fish and aquatic invertebrates on an acute basis. Acute LC_{50} values for fish range from 1.31 ppm for rainbow trout to 0.009 ppm for brook trout. The aquatic invertebrate LC_{50} value is .78 ppb for a daphnid and 1.4 ppb for a stonefly (Pteronarcys). The LC_{50} value ranges from 0.002 ppm for Atlantic salmon to 0.07 ppm for yellow perch for a 50% granular formulation.

Fish and aquatic invertebrates may be at risk from terrestrial (run-off and drift) and aquatic application of methoxychlor based on theoretical calculations . The estimated environmental concentrations (EECs) in aquatic environments range from 15.3 to 732 ppb. These EECs are above reported LC_{50} values for fish and aquatic invertebrate species at most application rates. Although these calculations indicate that aquatic species may be at risk, there are no field reports available suggesting a hazard exists. The Agency will conduct a hazard assessment upon receipt of acute and chronic aquatic studies, residue chemistry data, and environmental fate data.

There is sufficient information to characterize methoxychlor as relatively nontoxic to honey bees. Based on an acceptable laboratory acute contact study, the acute toxicity value = 24 ug/bee.

2. Environmental Fate

The Agency is unable to assess the environmental fate of methoxychlor because acceptable data are lacking. Data are required as set forth in Table A. Preliminary data indicate that methoxychlor is stable to : hydrolysis (half-life > 200 days); photodegradation in water (half-life of 4.5 months); and aerobic soil metabolism (half-life > 3 months in sandy loam soil). The half-life for anaerobic soil metabolism is reported at less than 1 month in sandy loam soil. Preliminary data also indicate that methoxychlor has a high adsorption rate to soil sediment (K_d value is 620).

The Agency is unable to assess the potential for methoxychlor to contaminate groundwater. Since methoxychlor is essentially insoluble in water and has a high adsorption rate to soil, groundwater contamination is likely to be minimal. Methoxychlor residues have not been reported for nearly 1300 wells that have been sampled in 10 States. Other pesticide monitoring systems (Storet) indicate that methoxychlor has been reported in 205 of 10859 samples from widespread localities. However, the validity of these reports has not been determined.

D. TOLERANCE ASSESSMENT

1. Tolerances Issued

Tolerances have been established for residues of methoxychlor in a variety of raw agricultural commodities and in meat, fat and meat byproducts (40 CFR 180.120). Tolerances are expressed in terms of methoxychlor per se. EPA has evaluated the residue and toxicology data supporting tolerances for the purpose of determining:

- 0 Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from the registered uses (including FIFRA section 24(c) uses).

- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).

- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

- Whether the tolerances are expressed accurately and in the current terminology.

The results of the Agency's evaluation are as follows:

a. Residue Data

1. No acceptable data are available on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of the pesticide. Data are required as set forth in Table A.

2. No acceptable analytical methodology for determining the levels of residues in plants and animals are available. Data are required as set forth in Table A.

3. No acceptable data are available on the stability of the compound in storage.

4. Data on the magnitude and levels of residues of the pesticide in individual raw agricultural commodities, animal products, and processed food and feed items are completely lacking. Data are required as set forth in Table A.

5. The Food and Drug Administration (FDA) Total Diet Studies as well as Surveillance and Compliance program for domestic and imported commodities employ methodology capable of determining residues of methoxychlor. Low levels of methoxychlor *per se* were observed in a limited number of commodities in the Total Diet Studies covering the period 4/82 through 4/86. Low levels of residues were observed in a small number of commodities for which no tolerance for methoxychlor residues have been established. FDA domestic and imported surveillance monitoring covering the period FY 78 through April 12, 1988 indicated a limited number of positive findings in various commodities.

b. Toxicology

The Preliminary Limiting Dose (PLD) of methoxychlor is .005 mg/kg/day. This is based on a rabbit teratology study with a No Observed Effect Level (NOEL) of 5 mg/kg/day for increased loss of litters and with an uncertainty factor of 1000 to account for inter- and intraspecies differences, poor quality of the study used and total incompleteness of the subchronic and chronic toxicity data base. The study is not considered to be adequate to define a NOEL for purposes of setting an Acceptable Daily Intake, since the experimental design was considered to be inadequate. It is being used on an interim basis for calculation of the PLD. A comparison of the TMRC with the ADI is not appropriate at this time due to the incompleteness of the toxicology and residue chemistry data bases.

The regulatory results of the Agency's review are set out in Section IV Regulatory Position and Rationale, items 7, 8, 9, and 10.

IV. REGULATORY POSITION AND RATIONALE

A. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on methoxychlor, the Agency has made the following determinations:

1. Methoxychlor is not being placed into Special Review at this time.

Rationale: Since there are so few acceptable studies available to support registration of products containing methoxychlor, the Agency is not yet able to make a determination as to whether any of the criteria of 40 CFR 154.7 have been met or exceeded.

2. The Agency will assess methoxychlor's potential for contaminating groundwater upon receipt of the required environmental fate data set forth in Table A of this Standard.

Rationale: The Agency is unable to assess the potential for methoxychlor to contaminate groundwater because the environmental fate of this chemical is uncharacterized. Groundwater contamination is unlikely due to methoxychlor's high rate of adsorption to soil sediment and insolubility in water. When data required in this Standard have been received and evaluated, the Agency will assess methoxychlor's potential for groundwater contamination.

3. The Agency is not establishing a longer reentry interval for agricultural uses of methoxychlor beyond the minimum reentry interval (sprays have dried, dusts have settled, and vapors have dispersed).

Rationale: Current labels for end-use products indicate that methoxychlor is of relatively low toxicity. Although the available data have not been reviewed by the Agency to determine whether they are valid or not, the Agency has no reason to believe that methoxychlor poses a risk to persons reentering treated fields after the minimum reentry interval. Moreover, there are no reports of acute poisonings to persons entering treated areas. For these reasons, the Agency has determined that a longer reentry interval beyond the minimum established reentry (sprays have dried, dusts have settled and vapors have dispersed) is not necessary for this chemical. Upon receipt and evaluation of the toxicology data requested in this Standard, the Agency will reevaluate its position regarding the need for reentry data/reentry intervals.

4. The U.S. Fish and Wildlife Service (USFWS) has determined that use of methoxychlor as a mosquito larvicide may jeopardize the continued existence of certain endangered species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy. The Agency will issue a PR Notice regarding any necessary labeling revisions when the program is implemented. No additional labeling is required at this time.

Rationale: Because of the demonstrated toxicity of methoxychlor to nontarget fish and aquatic invertebrates, methoxychlor was identified by the USFWS as likely to jeopardize certain endangered aquatic species when used as a mosquito larvicide. USFWS specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses. EPA is working with USFWS and other Federal and State agencies to implement the alternatives in a technically sound manner.

In order to reduce or eliminate exposure to these species to a point where the use does not result in jeopardy, EPA required special labeling on EPs of methoxychlor under PR Notice 87-4. Subsequent issuance of PR Notice 88-1 withdrew PR Notice 87-4 pending development of a more focused program to protect endangered species from adverse effects in the use of pesticides. When the program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

5. Methoxychlor products bear revised and updated labeling that accurately reflects hazards to terrestrial and aquatic organisms. The bee statement required under PR Notice 68-19 is no longer appropriate and must be removed from product labels.

Rationale: This requirement is based on laboratory findings that show that methoxychlor is very highly toxic to fish and aquatic invertebrates. Methoxychlor has been demonstrated to be relatively nontoxic to bees based on the results of an acceptable laboratory study.

6. The Agency is not classifying methoxychlor as a restricted use pesticide at this time.

Rationale: FIFRA section 3(d)(1)(C) provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects in man or the environment." The Agency is unable to determine if methoxychlor meets any of the risk criteria of 40 CFR 152.170 at this time due to extensive gaps in the data base. Upon receipt of data required under this Standard, the Agency will apply the criteria of 40 CFR 152.170 to determine if any uses of methoxychlor warrant restricted use classification.

7. The Agency will not approve any new food uses, including minor uses until the Agency has received data sufficient to perform a tolerance reassessment.

Rationale: None of the tolerances for methoxychlor is adequately supported. Plant and animal metabolism studies, residue studies, storage stability studies, processing studies and analytical methods are needed before the Agency can determine the adequacy of current tolerance levels and perform a tolerance reassessment. Because of the extensive residue chemistry data gaps, new food uses will not be granted until these data gaps have been filled.

8. The Agency will revise commodity definitions for certain raw agricultural commodities listed in 40 CFR 180.120.

Rationale: Certain listings in 40 CFR 180.120 are not appropriate and will be corrected by the Agency:

a. The tolerance listing for yams, boysenberries, dewberries and nectarines will be deleted, since tolerances for residues in or on other commodities apply to these commodities.

b. The listings for beets, radishes, rutabagas and turnips, and the leaves of these plants will be amended to reflect the appropriate commodity definition, beet roots, radishes, rutabagas, turnip tops, beet greens, radish tops, rutabaga tops, and turnip tops.

c. The listings for beans and peas will be amended to reflect the appropriate commodity definition beans (dried and succulent) and peas (dried and succulent).

d. The listing "grass for forage" will be amended to reflect the appropriate commodity definition grass forage.

e. The listing plums will be amended to reflect the appropriate commodity definition plums (fresh prunes).

f. The qualification "from preharvest and postharvest application" will be deleted from the listing for sweet potatoes. There is no postharvest use of methoxychlor for this commodity.

g. The tolerance for horseradish will be revoked since there is no registered use for this crop.

9. For the crops listed below, the registrant is given the choice of developing and submitting data in support of tolerances or of adding label restrictions against the feeding and grazing of treated crops to livestock. Each registrant must respond within 90 days of receipt of this Standard to inform the Agency whether he will propose tolerances or adopt the grazing/feeding restrictions. If he selects to adopt label restrictions, labeling submitted at the 9-month deadline must include the grazing/feeding prohibitions. Refer to Section V for acceptable wording of the grazing/feeding restrictions.

Pea vines and pea vine hay
Cowpea vines and cowpea hay
Soybean hay and straw
Corn forage
Pineapple forage

Rationale: Tolerances are required for raw agricultural commodities used as feed and forage for livestock and tolerances. Label restrictions prohibiting grazing/feeding prevent residues from occurring in meat and milk.

10. The current label restriction for asparagus which permits application up to the day of harvest provided the plant is washed and blanched must be deleted.

Rationale: Residue data are not available to support use on asparagus up to the day of harvest. The residue data required under this Standard will support application with a 3-day preharvest interval (PHI)

11. The Agency is requiring specific analysis of methoxychlor for the potential impurities 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane (DDT) and other structurally similar compounds.

Rationale: The Agency is requiring specific analysis of methoxychlor for these potential impurities because methoxychlor is an analogue of DDT.

12. The label for EPA SLN No. NV-800013 must be amended to incorporate a restriction against direct application to flowing water within 1/2 mile of a potable water intake.

Rationale: EPA SLN No. NV-800013 allows for direct application to NV river water. The restriction is needed to assure that the present 0.1 ppm Acceptable Residue Level in Drinking Water (ARLDW)[4] will not be exceeded under this use.

13. The Agency will not assign priority review for methoxychlor studies. Studies submitted in response to this Standard will be reviewed when the Agency conducts a second-round review of methoxychlor. Studies that are flagged in accordance with 40 CFR 158.34 will be given immediate review upon receipt.

Rationale: Available data do not suggest significant human health, environmental, or ecological concerns that justify priority review of data.

14. While data gaps are being filled, currently registered products containing methoxychlor may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Registration Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Even when authorized under FIFRA sections 3(c)(2)(B) and 3(c)(7), the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

V. REQUIRED LABELING STATEMENTS AND COMPLIANCE DATES

All products must bear appropriate labeling as specified in 40 CFR 156.10 and below.

Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after January 1990 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed or sold by any person after January 1991 unless that product bears amended labeling that complies with the requirements of FIFRA, as specified in this Standard.

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[4] An acceptable residue level in drinking water (ARLDW) of 0.1 ppm has been established under the Safe Drinking Water Act (Quality Criteria for Water, July 1986, USEPA, Washington, D.C. 20460., p. 164)

a. Manufacturing-Use Products (MPs)

1. The ingredient statement for MPs must declare the active ingredient as:

Methoxychlor: 1,1,1-trichloro-2,2-bis (4-methoxyphenyl)ethane

2. Labels for MPs must bear the following identifying phrase directly beneath the product name:

"An insecticide for formulating use only."

3. In the directions for use, the following statement must appear:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

4. In the directions for use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."[5]

5. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

6. The following statements are required to appear under the "Environmental Hazards" heading:

"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

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[5] The Use Index (EPA Compendium of Acceptable Uses) (for availability see Section I) lists all federally-registered uses of methoxychlor, as well as approved maximum application rates and frequencies. No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern.

b. End-Use Products (EPs)

1. The ingredient statement for EPs must declare the active ingredient as:

Methoxychlor: 1,1,1-trichloro-2, 2-bis(p-methoxyphenyl) ethane

2. All EPs allowing for nonaquatic uses (except seed treatment and forestry) must bear the following environmental hazards statement:

"This pesticide is toxic to fish and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.

3. All EPs allowing for seed treatment use must bear the following environmental hazards statement:

"This pesticide is toxic to fish and aquatic invertebrates. Cover or collect treated seeds spilled on soil surface. Do not contaminate water when disposing of equipment washwaters."

4. All EPs allowing for forestry use must bear the following environmental hazards statement:

"This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Aerial application over such sites is permissible only when they are not visible from above the tree canopy. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters."

5. All EPs allowing for aquatic use must bear the following environmental hazards statement:

"This pesticide is toxic to fish and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters."

6. The EPA SLN NV800013, allowing for use in flowing water, must bear the following restriction:

" Water treated with methoxychlor must not be released within 1/2 mile upstream of a potable water intake in flowing water (i.e., river or stream)."

7. All products allowing for outdoor use on agricultural sites must bear the following updated worker safety rules and reentry protection statements:

"Do not enter or allow entry into treated areas until [sprays have dried/dusts have settled/vapors have dispersed, as applicable] to perform hand labor tasks. A person may enter the area to perform other tasks only if the person is wearing the personal protective equipment listed on the label for a pesticide handler."

Do not apply this product in a way that will contact unprotected workers, either directly or through drift. Only protected handlers wearing long pants, long sleeved shirts, socks, shoes and chemical resistant gloves may be in the area during application."

8. All EPs allowing for use on peas must bear the following grazing and feeding restrictions:

"Do not graze or feed treated pea vines or pea hay to livestock."

9. All EPs allowing for use on cowpeas must bear the following grazing and feeding restrictions:

"Do not graze or feed treated cowpea vines or cowpea hay to livestock."

10. All EPs allowing for use on soybeans must bear the following grazing and feeding restrictions:

"Do not graze or feed treated soybean hay or straw to livestock."

11. All EPs allowing for use on corn must bear the following feeding restriction:

"Do not feed treated corn to livestock."

12. All EPs allowing for use on pineapples must bear the following feeding and grazing restrictions:

"Do not graze or feed treated pineapple forage to livestock."

13. The bee statement, "This product is toxic to bees and should not be applied when bees are actively visiting the area," required by PR Notice 68-19, must be deleted from end use product labels on which it appears.

14. All end use products bearing directions for direct application to livestock and poultry must be amended to include a maximum rate of application in terms of active ingredient per head or per unit area, or the equivalent which can be converted. In addition, a minimum interval between applications must be specified.

VI. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[6].

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[6] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[7], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use

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[7] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[8]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

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[8] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form

8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data

development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Develop-ment of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA sec. 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use

factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data require-ment applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data require-ments, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data require-ments for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registra-tion Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Methoxychlor Registration Standard

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?1/	Bibliographic Citation1/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission2/
Part 158, Subpart C - Product Chemistry						
Product Identity and Composition						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No		Yes3/	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No		Yes4/	9 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	No		Yes5/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No		Yes	9 Months
63-3 - Physical State	TGAI	All	No		Yes	9 Months
63-4 - Odor	TGAI	All	No		Yes	9 Months
63-5 - Melting Point	TGAI	All	No		Yes6/	9 Months
63-6 - Boiling Point	TGAI	All			Yes7/	9 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All			Yes	9 Months

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?1/	Bibliographic Citation1/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission2/
Part 158, Subpart C - Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-8 - Solubility	TGAI or PAI	All			Yes	9 Months
63-9 - Vapor Pressure	TGAI or PAI	All			Yes	9 Months
63-10 - Dissociation Constant	TGAI or PAI	N/A				
63-11 - Octanol/Water Partition Coefficient	PAI	All			Yes8/	9 Months
63-12 - pH	TGAI	All			Yes9/	9 Months
63-13 - Stability	TGAI	All			Yes	9 Months

Part 158, Subpart C - Product Chemistry Footnotes

1/Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/Due dates refer to number of months following receipt of this Registration Standard, unless otherwise indicated.

3/The following information must be provided: (i) the name and address of the producer of the technical grade of the active ingredient (TGAI): (ii) the brand name, trade name or other commercial designation, the name and address of the producer, and information concerning the composition of each starting material; (iii) a general characterization of the process (e.g., batch or continuous); (iv) a flow chart of the chemical equations of each intended reaction

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Part 158, Subpart C - Product Chemistry Footnotes (cont'd)

occurring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; (v) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (vi) a description of the equipment used; (vii) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; (viii) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced); and (ix) a description of the procedures used to assure consistent composition of the substance produced (quality control methods).

4/A discussion regarding the origin of the following potential impurities must be provided: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur during production, the possible degradation of ingredients after production, post-production reactions between ingredients, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures.

5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. Specific analysis for the potential impurities 1-chloro-1,2,2-tris(p-methoxyphenyl)ethylene (TACE), 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane (DDT), and its structurally similar compounds is required at levels < 0.1%. If the product is produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the method used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the TGAI must be provided.

6/Data on melting point are required if the technical chemical is a solid at room temperature.

7/Data on boiling point are required if the technical product is a liquid at room temperature.

8/Data on octanol/water partition coefficient are required if the technical chemical is organic and nonpolar.

9/Data on pH are required if the test substance is dispersible in water.

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Nature of the Residue (Metabolism) - Plants	PAIRA	Partially	00146645	Yes[2]	18 Months
171-4 - Nature of the Residue (Metabolism) - Livestock	PAIRA and plant metabolites	No		Yes[3]	18 Months
171-4 - Residue Analytical Methods	TGAI and metabolites	Partially	00070728,00070729, 00097051,00108733, 00113268,00113273, 00135287,00164734, 00164739	Reserved[4]	
71-4 - Storage Stability	TEP and metabolites	Partially	00164734	Yes	15 Months
171-4 - Magnitude of the Residue in Plants[5,6]					
- Root and Tuber Vegetables					
- Beet roots	TEP	No		Yes[7]	18 Months
- Carrots	TEP	No		Yes[8]	18 Months
- Horseradish	TEP	No		Yes[9]	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[6,7]					
- Root and Tuber Vegetables (cont'd)					
- Parsnips	TEP	No		Yes[10]	18 Months
- Potatoes (Processed)	TEP	No No		Yes[11] Yes[12]	18 Months 24 Months
- Radishes	TEP	No		Yes[13]	18 Months
- Rutabagas	TEP	No		Yes[14]	18 Months
- Sweet Potatoes	TEP	No		Yes[15]	18 Months
- Turnips	TEP	No		Yes[16]	18 Months
- Yams	TEP	No		Yes[17]	18 Months
- Leaves of Root and Tuber Vegetables					
- Beet greens	TEP	No		Yes[18]	18 Months
- Radish tops	TEP	No		Yes[19]	18 Months
- Rutabaga tops	TEP	No		Yes[20]	18 Months
- Turnip tops	TEP	No		Yes[21]	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]					
- Leafy Vegetables					
- Celery	TEP	No		Yes[21a]	18 Months
- Lettuce	TEP	No		Yes[22]	18 Months
- Spinach	TEP	No		Yes[23]	18 Months
- Brassica Leafy Vegetables					
- Broccoli	TEP	No		Yes[24]	18 Months
- Brussels sprouts	TEP	No		Yes[25]	18 Months
- Cabbage	TEP	No		Yes[26]	18 Months
- Cauliflower	TEP	No		Yes[27]	18 Months
- Collards	TEP	No		Yes[28]	18 Months
- Kale	TEP	No		Yes[29]	18 Months
- Kohlrabi	TEP	No		Yes[30]	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]					
- Legume Vegetables					
- Beans (succulent/dry)	TEP	No		Yes[31]	18 Months
(Processed)		No		Yes[32]	24 Months
- Peas (succulent/dry)	TEP	No		Yes[33]	18 Months
- Soybeans	TEP	No		Yes[34]	18 Months
(Processed)		No		Yes[35]	24 Months
- Foliage of Legume Vegetables					
- Cowpea vines/hay	TEP	No		Yes[36]	18 Months
- Soybean forage/hay	TEP	No		Yes[37]	18 Months
- Fruiting Vegetables					
- Eggplant	TEP	No		Yes[38]	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]/
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]/					
- Peppers	TEP	No		Yes[39]/	18 Months
- Tomatoes	TEP	No		Yes[40]/	18 Months
(Processed)		No		Yes[41]/	24 Months
Cucurbit Vegetables					
- Cucumbers	TEP	No		Yes[42]/	18 Months
- Melons	TEP	No		Yes[43]/	18 Months
- Pumpkins	TEP	No		Yes[44]/	18 Months
- Squash, summer	TEP	No		Yes[45]/	18 Months
- Pome Fruits					
- Apples	TEP	No		Yes[46]/	18 Months
(Processed)		No		Yes[47]/	24 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]					
- Pome Fruits (cont'd)					
- Pears	TEP	No		Yes[48]	18 Months
- Quinces	TEP	No		Yes[49]	18 Months
- Stone Fruits					
- Apricots	TEP	No		Yes[50]	18 Months
- Cherries	TEP	No		Yes[51]	18 Months
- Peaches	TEP	No		Yes[52]	18 Months
- Plums (fresh prunes)	TEP	No		Yes[53]	18 Months
(Processed)		No		Yes[54]	24 Months
- Small Fruits and Berries					
- Blackberries	TEP	No		Yes[55]	18 Months
- Blueberries	TEP	No		Yes[56]	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]					
- Small Fruits and Berries (cont'd)					
- Boysenberries, dewberries, loganberries, youngberries	TEP	No		Yes[57]	18 Months
- Cranberries	TEP	No		Yes[58]	18 Months
- Currants	TEP	No		Yes[59]	18 Months
- Gooseberries	TEP	No		Yes[60]	18 Months
- Grapes	TEP	No		Yes[61]	18 Months
(Processed)		No		Yes[62]	24 Months
- Raspberries	TEP	No		Yes[57]	18 Months
- Strawberries	TEP	No		Yes[63]	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]/
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]/					
- Cereal Grains					
- Corn, fresh	TEP	No		Yes[64]/	18 Months
(Processed)		No		Yes[65]/	24 Months
- Grass Forage, Fodder, and Hay					
- Grass, forage and hay	TEP	No		Yes[66]/	18 months
- Nongrass Animal Feeds					
- Alfalfa forage and hay	TEP	No		Yes[67]/	18 Months
- Clover forage and hay	TEP	No		Yes[68]/	18 Months
- Miscellaneous Commodities					
- Asparagus	TEP	No		Yes[69]/	18 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]/
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5,6]/					
- Miscellaneous Commodities (cont'd)					
- Mushrooms	TEP	No		Yes[70]/	18 Months
- Peanuts	TEP	No		Yes[71]/	18 Months
(Processed)		No		Yes[72]/	24 Months
- Pineapples	TEP	No		Yes[73]/	18 Months
(Processed)		No		Yes[74]/	24 Months
- Crops with Registered Seed Treatments Only	PAIRA, TEP	No		Yes[75]/	18 Months
- Crops Grown Solely for Seed					
- Vetch	TEP	No		Yes[76]/	18 Months
171-4 - Magnitude of Residue in Stored Commodities	TEP	Partially	00089808,00093382	Yes[77]/	18 Months
(Processed)		No		Yes[78]/	24 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[5.6]					
171-4 - Magnitude of Residue in Meat/Milk/Poultry/ Eggs	TGAI or plant metabolites	Partially	00025687,00089064, 00105471,00113273, 00127393,05005125	Reserved[5.79]	
171-4 - Magnitude of Residue in Potable Water/Fish	PAIRA, EP	No		Yes[5.80]	15 Months
171-4 - Magnitude of Residue Irrigated Crops	EP	No	00135287	Yes[5.81]	18 Months
171-4 - Magnitude of Residue Food Handling Establishments	EP	No		Yes[5.82]	12 Months

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158.240 Residue Chemistry (Footnotes)

1/Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/Data are required depicting the uptake, distribution, and metabolism of ring-labeled [^{14}C]methoxychlor in or on three dissimilar food crops (e.g., a root crop, oilseed crop, and a leafy vegetable). If metabolism is not similar in the three crops, additional studies using other crops may be required. A completely characterized test substance representative of technical methoxychlor (including impurities) used in commercial formulations must be applied foliarly several times up to and including the day of harvest at rates sufficiently high to permit characterization of ^{14}C-residues. The identities and quantities of residues in or on mature plant parts must be determined in order

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

to elucidate terminal residues. Representative samples from the required metabolism studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

3/Metabolism studies utilizing ruminants and poultry are required. Animals must be dosed orally for a minimum of 3 days with ring-labeled [^{14}C]methoxychlor at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern. In addition, ruminants, poultry, and swine must be treated dermally with ring-labeled [^{14}C]methoxychlor at a concentration that will result in sufficient residues in the tissues for characterization. Animals must be sacrificed 24 hours after treatment and residues characterized in muscle, fat, kidney, liver, and skin (poultry and swine only). Representative samples from these studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

4/The nature of the residue in plants and animals has not been adequately described. If the metabolism studies requested in the sections "Nature of the Residue in Plants" and "Nature of the Residue in Animals" reveal the presence of additional metabolites of concern in or on plant and/or animal commodities, additional validated methods for data collection and tolerance enforcement will be required.

5/The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant and animal commodities. Storage stability data in support of previously submitted residue data are required for only those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in methoxychlor residue levels in commodities stored under the range of conditions and for the range in intervals specified. Crop samples bearing measurable weathered residues or fortified with methoxychlor and fortified meat, milk, and egg samples must be analyzed immediately after harvest or fortification and again after storage intervals that represent actual residue sample storage conditions and allow for reasonable unforeseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August 1987 Position Document on the Effects of Storage on Validity of Pesticide Residue Data available from NTIS under order no. PB88112362/AS.

6/Unless otherwise specified, each formulation class registered for use on a given crop must be represented in separate tests. Data on aerial application must be provided for one or more representative crops from each crop group having members with registered methoxychlor uses allowing aerial application. If residues resulting from aerial application exceed those from ground application, additional residue tests may be required on other crops. The requested residue data must reflect the maximum number of applications and minimum interval between treatments specified on the labels or proposed by the registrant to appear on the labels.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

7/Data are required depicting methoxychlor residues of concern in or on beet roots harvested 7 days following multiple foliar applications of a representative D, WP/D or F1C, and an EC formulation at 2.25 ai/A and 14 days following applications of these formulations at 5 lb ai/A, or at the maximum rate permitted for a given formulation class. Tests must be conducted in NY, OR, and TX.

8/Data are required depicting methoxychlor residues of concern in or on carrots harvested 7 days following multiple foliar applications of a representative WP/D or F1C, and an EC formulation at 2.25 ai/A and 14 days following applications of these formulations at 5 lb ai/A, or at the maximum rate permitted for a given formulation class. Tests must be conducted in CA, FL, and TX.

9/The registrant must propose directions for use of methoxychlor on horseradish and submit appropriate supporting residue data or the established tolerance will be revoked.

10/Data are required to determine methoxychlor residues of concern in or on parsnips. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on parsnips; or b) indicate support of the use on turnip and request that the required data for that use pattern be used to support the use on parsnips. A maximum number of applications per season or a maximum seasonal foliar use rate must be proposed. An appropriate tolerance level proposal for residues of methoxychlor in or on parsnips is also required.

11/Data are required depicting methoxychlor residues of concern in or on potatoes harvested on the day of the last of multiple foliar applications of representative D, WP/D, and EC formulations at 2.25 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in ID, WA, ME, OR, and WI.

12/Data are required depicting residues of methoxychlor in chips, granules, and wet and dry peel from potatoes bearing measurable weathered residues. If residues concentrate in any of these commodities, an appropriate feed/food additive tolerance must be proposed.

13/Data are required depicting methoxychlor residues of concern in or on radishes harvested 7 days following multiple foliar applications of a representative WP/D or F1C, and an EC formulation at 5 lb ai/A. Tests must be conducted in FL and MI.

14/Data are required depicting methoxychlor residues of concern in or on rutabagas harvested 7 days following multiple foliar applications of a representative WP/D or F1C, and an EC formulation at 2.25 lb ai/A and 14 days following applications of these formulations at 5 lb ai/A, or at the maximum rate permitted for a given formulation class. Tests must be conducted in MN, WA, and WI.

15/Data are required depicting methoxychlor residues of concern in or on sweet potatoes harvested on the day of the last of multiple foliar applications of the 10% D formulation, the 50% WP/D, and a representative EC formulation at 2.25 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in CA, LA, and NC.

16/Data are required depicting methoxychlor residues of concern in or on turnips harvested 1 day following multiple foliar applications of a representative D, WP/D, or EC formulation at 1.75 lb ai/A, 7 days following applications of these formulations at 2.25 lb ai/A, and 14 days following application of these formulations at 5 lb ai/A. Tests must be conducted in CA, PA, GA, and TX.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

17/Data are required to determine methoxychlor residues of concern in or on yams. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on yams; or b) indicate support of the use on sweet potatoes and request that the required data for that use pattern be used to support the use on yams.

18/Data are required to determine methoxychlor residues of concern in or on beet greens. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either a) request a determination of the specific formulations, rates, and application schedule to be tested on beet greens; or b) indicate support of the use on turnip tops and request that the required data for that use pattern be used to support the use on beet greens.

19/Data are required to determine methoxychlor residues of concern in or on radish tops. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on radish tops; or b) indicate support of the use on turnip tops and request that the required data for that use pattern be used to support the use on radish tops.

20/Data are required to determine methoxychlor residues of concern in or on rutabaga tops. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on rutabaga tops; or b) indicate support of the use on turnip tops and request that the required data for that use pattern be used to support the use on rutabaga tops.

21/Data are required depicting methoxychlor residues of concern in or on turnip tops harvested 14 days following multiple foliar applications of representative D, WP/D, and EC formulations at 5 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in TN, FL, GA, AL, and TX.

21a/Residue data depicting residues of methoxychlor in or on untrimmed celery treated foliarly at 0.5 oz/100 sq. ft. of a 5% D (EPA Reg. No. 8580-283) and harvested 7 days after application are required. Data must be obtained from the states of CA, FL, and MI. A maximum number of applications per season or a maximum seasonal foliar use rate must be proposed. An appropriate tolerance level proposal for levels of methoxychlor in or on celery is also required.

22/Data are required depicting methoxychlor residues of concern in or on lettuce (with and without wrapper leaves) harvested 14 days after the last of multiple foliar applications of a D and EC formulation at 2.25 lb ai/A and the 50% WP/D formulation at 2.25 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in CA.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

23/Data are required depicting methoxychlor residues of concern in or on spinach harvested 14 days after the last of multiple foliar applications of the 5% D, the 50% WP/D, and a representative EC formulation at 5 lb ai/A. Tests must be conducted in CA, TX, and NJ.

24/Data are required depicting methoxychlor residues of concern in or on broccoli harvested 14 days following the last of multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in CA and TX.

25/Data are required to determine methoxychlor residues of concern in or on Brussels sprouts. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on Brussels sprouts; or b) indicate support of the use on broccoli and request that the required data for that use pattern be used to support the use on Brussels sprouts.

26/Data are required depicting methoxychlor residues of concern in or on cabbage (with and without wrapper leaves) harvested 7 days following the last of multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in CA, FL, NY, TX, and WI.

27/Data are required depicting methoxychlor residues of concern in or on cauliflower harvested 7 days following the last of multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in CA, NY, and TX.

28/Data are required depicting methoxychlor residues of concern in or on collards harvested 14 days following the last of multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in AZ and GA.

29/Data are required to determine methoxychlor residues of concern in or on kale. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on kale; or b) indicate support of the use on collards and request that the required data for that use pattern be used to support the use on kale.

30/Data are required to determine methoxychlor residues of concern in or on kohlrabi. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on kohlrabi; or b) indicate support of the use on broccoli and request that the required data for that use pattern be used to support the use on kohlrabi.

31/Data are required depicting methoxychlor residues of concern in or on beans (both succulent and dry) harvested 3 days after the last of multiple foliar applications (at 7-day intervals) of a representative EC formulation, a FlC or WP/D formulation, and a D formulation at 5 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in 1) CA, OR or ID; 2) MI or NE; 3) NY; and 4) WI.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

32/Data are required depicting methoxychlor residues in or on cannery waste processed from beans bearing measurable, weathered residues. If the data indicate a potential for residue concentration in this commodity, an appropriate food additive tolerance must be proposed.

33/Data are required depicting methoxychlor residues of concern in or on peas (both succulent and dry) harvested 7 days after the last of multiple foliar applications (at 7-day intervals) of a representative EC formulation, a F1C or WP/D formulation, and a D formulation at 5 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in MN, WA, and WI. Since pea vines and pea vine hay are raw agricultural commodities (RACs), the registrant must propose tolerances for residues of methoxychlor in or on pea vines and pea vine hay and submit appropriate supporting residue data. A pregrazing interval must also be specified. Alternatively, the registrant may elect to propose a label amendment that restricts feeding or grazing treated pea vines and pea vine hay to livestock.

34/A tolerance must be proposed, and data must be submitted (in support of the tolerance) depicting methoxychlor residues in or on soybeans harvested 7 days following the last of multiple foliar applications of a representative D, EC, and a WP/D formulation at 3 lb ai/A. Tests must be conducted in AZ, IL, IN, and IA.

35/A processing study depicting methoxychlor residues in or on products (meal, hulls, soapstock, crude oil, and refined oil) and in grain dust from the processing of soybeans bearing measurable weathered residues is required. If the data indicate a potential for residue concentration in any of these commodities, an appropriate food additive tolerance must be proposed.

36/Data are required depicting methoxychlor residues of concern in or on cowpea forage and cowpea hay harvested 3 days after the last of multiple foliar applications of representative D, EC, and WP/D or F1C formulations at 5 lb ai/A or at the maximum rate and minimum PHI permitted for a given formulation class. Tests must be conducted in CA and TX. The registrant must propose a tolerance for residues of methoxychlor in or on cowpea hay. Alternatively, the registrant may propose a label amendment restricting the feeding or grazing of treated cowpea hay and vines to livestock.

37/Data are required depicting methoxychlor residues in or on soybean forage harvested 7 days following the last of multiple foliar applications of a representative D, EC, and a WP/D formulation at 3 lb ai/A. Tests must be conducted in AZ, IL, IN, and IA. Since soybean hay and straw are RACs, the registrant must propose tolerances for residues of methoxychlor in or on soybean hay and straw and submit appropriate supporting residue data. Alternatively, the registrant may propose a label amendment that restricts feeding or grazing of treated soybean hay and straw to livestock.

38/Data are required to determine methoxychlor residues of concern in or on eggplant. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on eggplant; or b) indicate support of the use on tomatoes and request that the required data for that use pattern be used to support the use on eggplant.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

39/Data are required depicting methoxychlor residues of concern in or on peppers harvested 1 day following the last of multiple foliar applications of representative D, WP/D or F1C, and EC formulations at 1.75 lb ai/A and 7 days following applications of the D and EC formulations at 2.25 lb ai/A and the WP/D OR F1C formulation at 2.25 lb ai/A. Tests must be conducted in CA, FL, NC, and TX.

40/Data are required depicting methoxychlor residues of concern in or on tomatoes harvested 7 days following the last of multiple foliar applications of representative D, EC, and WP/D or F1C formulations at 3.5 lb ai/A or at the highest rate permitted for a given formulation class. Data are also required depicting these residues in or on tomatoes harvested 1 day following the last of multiple foliar applications of these formulations at 1.75 lb ai/A or at the maximum rate permitted for a given formulation class. The tests must be conducted in CA and FL.

41/A processing study depicting residues of methoxychlor in dry pomace, puree, catsup, and juice processed from tomatoes bearing measurable weathered residues is required. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

42/Data are required depicting methoxychlor residues of concern in or on cucumbers harvested 7 days following multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum registered rate permitted for a given formulation class. Tests must be conducted in CA, FL, MI, NC, and TX.

43/Data are required depicting methoxychlor residues of concern in or on melons harvested 7 days following multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum registered rate permitted for a given formulation class. Data are also required depicting these residues in samples harvested 1 day following the last of multiple foliar applications of these same formulations at 2 lb ai/A or at the maximum rate for a given formulation class permitted 1 day before harvest. Tests must be conducted in CA and TX.

44/Data are required to determine methoxychlor residues of concern in or on pumpkins. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on pumpkins; or b) indicate support of the use on melons and request that the required data for that use pattern be used to support the use on pumpkins.

45/Data are required depicting methoxychlor residues of concern in or on summer squash harvested 7 days following the last of multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 5 lb ai/A or the maximum registered rate permitted for a given formulation class. Data are also required depicting these residues in samples harvested 1 day following the last of multiple foliar applications of these same formulations at 2 lb ai/A or at the maximum rate for a given formulation class permitted 1 day before harvest. Tests must be conducted in CA, FL, NJ, and TX.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

46/Data are required depicting methoxychlor residues of concern in or on apples harvested 7 days following the last of multiple foliar applications of the 50% WP/D formulation at 10 lb ai/A and a representative EC formulation at 12 lb ai/A. Tests must be conducted in CA, MI, NY, and WA.

47/Data are required depicting methoxychlor residues of concern in dry apple pomace and juice processed from apples bearing measurable weathered residues. If residues concentrate in any of these processed commodities, an appropriate food/feed additive tolerance must be proposed.

48/Data are required depicting methoxychlor residues of concern in or on pears harvested 7 days following the last of multiple foliar applications of the 50% WP/D at 10 lb ai/A and a representative EC formulation at 12 lb ai/A. Tests must be conducted in CA.

49/Data are required to determine methoxychlor residues of concern in or on quinces. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on quinces; or b) indicate support of the use on apples and request that the required data for that use pattern be used to support the use on quinces.

50/Data are required to determine methoxychlor residues of concern in or on apricots. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on apricots; or b) indicate support of the use on peaches and request that the required data for that use pattern be used to support the use on apricots.

51/Data are required depicting methoxychlor residues of concern in or on cherries harvested 7 days following the last of multiple applications of the 50% WP or WP/D formulations at 10 lb ai/a and a representative EC and F1C formulation at 12 lb ai/A or the maximum rate permitted for a given formulation class. Tests on sweet cherries must be conducted in CA, MI, and WA. Tests on tart cherries must be conducted in MI.

52/Data are required depicting methoxychlor residues of concern in or on peaches harvested 21 days following the last of multiple applications of the 50% WP or WP/D formulations at 10 lb ai/A and a representative EC and F1C formulation at 12 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in CA and GA or SC.

53/Data are required depicting methoxychlor residues of concern in or on plums harvested 7 days following the last of multiple applications of the 50% WP or WP/D formulations at 10 lb ai/A and a representative EC and F1C formulation at 12 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in MI and OR.

54/A processing study is required depicting methoxychlor residues of concern in dried prunes processed from fresh prunes bearing measurable weathered residues. If residues concentrate in this item, an appropriate food additive tolerance must be proposed.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

55/Data are required depicting methoxychlor residues of concern in or on blackberries harvested 14 days following the last of multiple foliar applications of the 10% D, a representative EC formulation, and the 50% WP/D or 4 lb/gal F1C formulation at 5 lb ai/A or at the maximum rate permitted for a given formulation class 14 days prior to harvest. Data are also required depicting these same residues in or on blackberries harvested 3 days following the last of multiple foliar applications of a representative formulation of each class at 1.75 lb ai/A or at the maximum rate permitted for a given formulation class 3 days prior to harvest. The tests must be conducted in OR and CA. Data are also required depicting methoxychlor residues of concern in or on blackberries harvested on the day of the last of multiple foliar applications of the 2 lb/gal EC formulation at 1.75 lb ai/A. The test must be conducted in OR. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. OR-780031.

56/Data are required depicting methoxychlor residues of concern in or on blueberries harvested 14 days following the last of multiple foliar applications of representative D, EC, and the 50% WP/D or the 4 lb/gal F1C formulations at 5 lb ai/A or at the maximum rate permitted for a given formulation class. Tests must be conducted in MI, NJ, and NC.

57/Data are required to determine methoxychlor residues of concern in or on these berries. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on these berries; or b) indicate support of the use on blackberries and request that the required data for that use pattern be used to support the use on these berries.

58/Data are required depicting residues of methoxychlor in or on cranberries harvested 14 days following the last of multiple foliar applications of a representative EC and the 50% WP/D or 4 lb/gal F1C formulation at 5 lb ai/A or at the maximum rate permitted for a given formulation class. The tests must be conducted in MA and WI.

59/Data are required to determine methoxychlor residues of concern in or on currants. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on currants; or b) indicate support of the use on blueberries and request that the required data for that use pattern be used to support the use on currants.

60/Data are required to determine methoxychlor residues of concern in or on gooseberries. The registrant must contact the Agency within the allowed ninety (90) day period indicating his intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on gooseberries; or b) indicate support of the use on blueberries and request that the required data for that use pattern be used to support the use on gooseberries.

61/Data are required depicting methoxychlor residues of concern in or on grapes harvested 14 days following the last of multiple foliar applications of a representative EC and a WP/D or F1C formulation at 6 lb ai/A or the maximum rate permitted for a given formulation class. The tests must be conducted in CA and NY. Data are also required depicting methoxychlor residues of concern in or on grapes harvested on the day of the last of multiple foliar applications of the 50% WP formulation at 3 lb ai/A. The tests must be conducted in AR. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. AR-770006.

62/Data are required depicting the potential for residue concentration in dry pomace, raisins, and raisin waste processed from grapes bearing measurable weathered residues. If residues concentrate in any of these commodities, an appropriate food/feed additive tolerance must be proposed.

63/Data depicting methoxychlor residues of concern in or on strawberries harvested 14 days following the last of multiple foliar applications of a representative D formulation, a F1C formulation or the 50% WP formulation, and a representative EC formulation at 5 lb ai/A or at the maximum rate permitted for a given formulation class 14 days before harvest. In addition, data are required depicting residues in or on strawberries harvested 3 days after the last of multiple foliar applications of each of these formulations at 1.75 lb ai/A or at the maximum rate permitted for a given formulation class 3 days before harvest. The tests must be conducted in CA and FL.

64/Data are required depicting methoxychlor residues of concern in or on sweet corn harvested 7 days following the last of multiple foliar applications of representative EC and either F1C or WP/D formulations at 2.25 lb ai/A or the maximum rate for a given formulation class permitted 7 days prior to harvest. In addition, data are required depicting residues in or on corn harvested 14 days following the last of multiple foliar applications of these same formulations at 3 lb ai/A or the maximum rate for a given formulation class. Tests must be conducted in MN, FL, IL or WI, and OR or CA. The registrant must amend all pertinent product labels to specify whether use on field corn is intended. If any labels are amended to include field corn, appropriate supporting residue data for corn grain will be required. Since forage is an RAC of fresh sweet corn, a tolerance must be proposed for corn forage and appropriate supporting residue data submitted. Alternatively, the registrant may elect to propose a restriction on the feeding of this commodity to livestock.

65/Data are required depicting methoxychlor residues of concern in cannery waste processed from sweet corn bearing measurable weathered residues. If residues concentrate, an appropriate feed additive tolerance must be proposed. The requirement for cannery waste data may be waived if the registrant elects to submit the appropriate sweet corn forage residue data.

66/Data are required depicting methoxychlor residues of concern in or on Bermudagrass, bluegrass, and bromegrass or fescue (as fresh grass and hay) harvested 7 days following the last of multiple foliar applications of the 5% D formulation, the 50% WP/D formulation, and a representative EC formulation at 3 lb ai/A. The registrant must propose an appropriate tolerance for methoxychlor residues of concern in or on grass hay. Tests must be conducted in 1) ID, MT, OR or WA; 2) KS, MO, OK or TX; 3), KY or TN; 4) AL, GA or MS, IA, NE, MN, ND or SD; and 5) NY or PA.

67/Data are required depicting methoxychlor residues of concern in or on alfalfa forage and hay (ca. 10% moisture content) harvested 7 days following the last of multiple foliar applications of the 5% D formulation, a representative EC formulation, and the 50% WP/D or 4 lb/gal F1C formulation at 4.5 lb ai/A. The registrant must propose an appropriate tolerance for residues of methoxychlor in or on alfalfa hay. Tests must be conducted in CA, NY, and WI.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

68/Data are required depicting methoxychlor residues of concern in or on clover forage and hay harvested 7 days following the last of multiple foliar applications of a representative EC, the 50% WP/D formulation, and the 5% D formulation at 3 lb ai/A. Test must be conducted in 1) ID, MI, MN, MS or GA; 2) NY; 3) OK; and 4) WI. The registrant must propose an appropriate tolerance for methoxychlor residues of concern in or on clover hay and submit appropriate supporting residue data.

69/Data are required depicting methoxychlor residues of concern in or on asparagus harvested 3 and 7 days following the last of multiple foliar applications of a D formulation, a representative EC formulation, and the 50% WP/D formulation at 2.25 and 3.5 lb ai/A, respectively. Tests must be conducted in CA or WA and MI. The registrant must amend all pertinent labels removing the requirement of washing and blanching of samples when harvested prior to 3 days following application at rates of up to 2.25 lb ai/A. If the registrant's intent is to allow applications up to the day of harvest, then appropriate residue data must be submitted.

70/Data are required depicting methoxychlor residues of concern in or on mushrooms resulting from applications to mushroom houses with the 50% WP/D and the 4 lb/gal EC formulations at 5.33 oz ai/500 sq ft. Applications must be made daily for 7 days up to 7 days prior to mushroom emergence.

71/Data are required depicting methoxychlor residues of concern in or on mature peanuts and peanut forage harvested 7 days following the last of multiple foliar applications of the 5% D formulation, the 50% WP/D formulation, and a representative EC formulation at 3 lb ai/A or the maximum rate permitted for a given formulation class. Tests must be conducted in AL, GA, and TX. The registrant must propose tolerances for methoxychlor residues of concern in or on the RACs hulls and hay of peanuts and submit appropriate supporting residue data.

72/A processing study is required depicting methoxychlor residues in products (meal, soapstock, crude oil, and refined oil) processed from peanuts bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

73/Data are required depicting methoxychlor residues of concern in or on pineapples harvested 7 days following the last of multiple foliar applications of the 2 lb/gal EC formulation at 2 lb ai/A. Tests must be conducted in HI. Since pineapple forage is an RAC, the registrant must either propose a tolerance for pineapple forage and provide the appropriate supporting residue data, or propose a feeding or grazing restriction.

74/A processing study depicting residues of methoxychlor in products (bran and juice) processed from pineapples bearing measurable weathered residues is required. If residues concentrate in any product, an appropriate food/ feed additive tolerance must be proposed.

75/Data are required depicting the uptake, distribution, metabolism, and total terminal residues of ring-labeled [^{14}C]methoxychlor in the food/feed commodities of cotton, flax, lespedeza, mustard, okra, onion, rice, safflower, sunflower, and wheat (representative crops that are registered for seed treatment) resulting from seed treatment with [^{14}C]methoxychlor. Studies must be conducted at the respective maximum labeled rates for the seed treatments of these respective crops. Data are also required depicting methoxychlor residues in or on cotton, flax, lespedeza, mustard,

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

okra, onion, rice, safflower, sunflower, and wheat resulting from seed treated with methoxychlor according to the label directions of the product having the maximum permissible use rate. Samples of all RACs for each crop must be collected at the shortest interval after planting at which time they could be used for food or feed purposes. Tolerances must be proposed that reflect either the maximum expected residue levels or, if no measurable residues are detected, the limit of detection of the analytical method. All processing studies, if needed, must utilize RACs bearing measurable weathered residues.

76/The registrant must propose appropriate tolerances for residues of methoxychlor in or on vetch forage and hay. Samples should be taken at regular intervals following multiple foliar applications of the 2 lb/gal EC formulation at 1 lb ai/A to determine a reasonable PHI. Applications must be made by ground equipment in 20 gal/A and by aerial equipment (in a separate test) in 5 gal/A. The registrant must propose a maximum number of applications per season or a maximum season use rate. Tests should be conducted in OR to support the SLN. Residues should be determined in hay and in forage from which hay was prepared. Alternatively, the registrant may elect to cancel the existing use.

77/Data are required depicting methoxychlor residues of concern in or on corn and wheat grain following the full series of registered applications (empty-bin, surface spray, and fog) at both the 1 and 2X rates. The galvanized metal bins used for storage should hold a minimum of 50 bushels of grain. Grain must be loaded in the bin 24 hours following a residual wall application of an EC and the 4 lb/gal FlC formulations at 0.4 lb ai/1000 sq ft. After loading, the surface of wheat and corn must be treated with the 2 lb/gal EC and 4 lb/gal FlC formulations at 0.4 lb ai/1000 sq ft grain surface, followed by a fog application of the 5% RTU formulation to the bin at 4 fl oz product/5000 cu ft. A separate test must be conducted at the 2X rate (0.8 lb ai/1000 sq ft for the wall treatment, and 0.8 lb ai/1000 sq ft and 8 fl oz product/5000 cu ft for the surface and fog applications, respectively). Samples must be taken from the center of the bin, at the wall, and off the top. Multiple sampling must be done immediately after the final (fog) treatment and at weekly intervals thereafter for 5 weeks. Sample storage conditions and intervals must be reported. The registrant must propose label amendments for the 4 lb/gal FlC formulation reflecting use on specific stored grains. Data are required depicting methoxychlor residues of concern in or on sorghum and rice grain following the full series of registered applications (empty-bin and surface spray) at both the 1 and 2X rates. The galvanized metal bins used for storage should hold a minimum of 50 bushels of grain. Grain must be loaded in the bin 24 hours following a residual wall application of an EC and the 4 lb/gal FlC formulations at 0.4 lb ai/1000 sq ft. After loading, the surface of sorghum and rice must be treated with the 4 lb/gal FlC formulation at 0.4 lb ai/1000 sq ft grain surface. A separate test must be conducted at the 2X rate (0.8 lb ai/1000 sq ft for the wall treatment and 0.8 lb ai/1000 sq ft for the surface application). Samples must be taken from the center of the bin, at the wall, and off the top. Multiple sampling must be done immediately after the final (surface) treatment and at weekly intervals thereafter for 5 weeks. Sample storage conditions and intervals must be reported. When an appropriate tolerance for residues in or on stored treated wheat grain is determined, a food/feed additive tolerance must be established for wheat grain dust.

Table A
Generic Data Requirements for Methoxychlor (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

78/A processing study is required depicting methoxychlor residues of concern in the milled product middlings from the processing of wheat bearing measurable weathered residues. If residues concentrate, an appropriate food/feed additive tolerance must be proposed. A tolerance must be proposed and appropriate supporting residue data submitted for corn grain dust based on the following treatment regimen: corn grain dust must be collected immediately following treatment of grain with the 2 lb/gal EC formulation at 1 and 2 lb ai/1000 bushels grain (1 and 2X the maximum amount that the grain would be exposed to, assuming that a surface spray extends to a depth of 6 inches in a storage bin). Applications may be made while tumbling approximately 10 bushels of grain in a cement mixer; approximately 1 lb of grain dust should be collected as it is produced while the grain is tumbled. Sample storage intervals and conditions must be reported. Untreated control samples should be collected prior to treatment. A processing study is required depicting methoxychlor residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, and crude and refined oils) from the processing of field corn bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. A processing study is required depicting methoxychlor residues of concern in milled products (hulls, bran, and polished rice) and grain dust (see corn grain dust protocol above) from the processing of rice bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. A processing study is required depicting methoxychlor residues of concern in milled products (flour and starch) and grain dust (see corn grain dust protocol above) from the processing of sorghum bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

79/The registrant must amend all pertinent labels to specify a maximum application rate and a minimum interval between applications. The rates must be expressed in terms of amount of active ingredient per head or per unit area, or the equivalent which can readily be converted to such. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of residue in livestock and poultry will be determined. Depending on the results of the required metabolism studies, additional feeding and dermal residue studies may be needed. The dermal studies will be required for each species for which a dermal use is registered.

80/To support the NV registration (EPA SLN No. NV-800013), a metabolism study must be submitted in which fish are exposed (for at least 3 days) to water containing [^{14}C]methoxychlor at 0.2 ppm or a concentration sufficiently high to permit complete quantification and characterization of ^{14}C-residues in edible tissues (flesh and skin). Representative samples must also be analyzed by proposed enforcement methods to ascertain that all residues of concern are determined. In addition, the registrant must propose a tolerance or an exemption from the requirement of a tolerance for methoxychlor in fish following registered aquatic use. This study should be completed and submitted prior to initiation of the fish residue trial required below. Alternatively, the registrant may elect to cancel this use.

To support the NV registration (EPA SLN No. NV-800013), data must be submitted depicting methoxychlor residues of concern in bottom feeders (e.g., catfish) and predators (e.g., bass) harvested after 1, 3, 7, and 10 days of exposure to water containing 0.2 ppm methoxychlor. The registrant must propose a maximum seasonal use rate or limit on the number of applications per season. Alternatively, the registrant may elect to cancel this use. Data are required depicting methoxychlor residues of concern in (i) NV river water immediately following direct treatments, at 10-day intervals by "drip station method" over a 15-minute period, with the 2 lb/gal EC formulation at 0.2 ppm; and (ii) ID and UT irrigation waters immediately following direct treatments with the 2 lb/gal EC formulation at 0.3 ppm (1.69 lb ai/100 cu ft/second of water flow for 15 minutes). The registrant must also implement the following label restrictions: Water treated with methoxychlor must not be released within 1/2 mile upstream of a potable water intake in flowing water (i.e., river or stream) or within 1/2 mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.

81/Data are required depicting methoxychlor residue of concern in or on a representative irrigated commodity from each crop group grown in the States of ID and UT which utilize either soil or overhead irrigation as a standard agricultural practice (i.e., multiple irrigation) using water containing 0.3 ppm of methoxychlor. Crops must be harvested immediately after the final irrigation. In addition, the registrant must propose a maximum number of times a field may be irrigated with treated water for each crop. The submitted data must reflect this maximum. Tests must be conducted in ID and UT. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN Nos. ID-780020 and UT-790012.

82/Data are required depicting methoxychlor residues of concern in food products resulting from applications of methoxychlor in grain mills, food processing plants, and peanut warehouses. Tests are required in these establishments utilizing an EC and an SC/L formulation as a crack and crevice treatment, and an RTU as fog treatment. Tests must represent worst case scenarios for potential residue contamination of food products which might include, but not be limited to, some of the following: (i) particulate aerosol contact with packaged products present at the time of treatment; (ii) contact of packaged or stored foods with treated surfaces, such as flour sacks stacked on treated floor surfaces in storage areas or peanuts (with and without shells) stored in treated warehouses; (iii) treatment occurring near stacks of new or cleaned product containers that are then filled without being cleaned; or (iv) tracking of residues by insects or rodents from treated areas to food or food contact surfaces.

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D,E, G,H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B,C,D,G	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A,G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		Reserved2/	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,E,G,H	No		Yes	27 Months (12 Months - Progress Report)
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months (12 Months - Progress Report)
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,D,G	No		Yes	27 Months (12 Months - Progress Report)
162-4 - Aerobic Aquatic	TGAI or PAIRA	C,D	No		Yes	27 Months (12 Months - Progress Report)

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.290 Environmental Fate						
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B,C,D,E, G,H	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	A,E	No		Reserved2/	
163-3 - Volatility (Field)	TEP	A,E	No		Reserved2/	
Dissipation Studies - Field						
164-1 - Soil	TEP	A,B,H	No		No3/	
164-2 - Aquatic (Sediment)	TEP	C,D	No		Yes	27 Months (12 Months - Progress Report)
164-3 - Forestry	TEP	G	No		Yes	27 Months (12 Months - Progress Report)
164-4 - Combination and Tank Mixes	TEP	N/A				
164-5 - Soil, Long-Term	TEP	A,B,C	No		Yes3/	39 Months4/ (Acceptable Protocol 90 Days (12 Months - Progress Report)

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.290 Environmental Fate						
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No		Yes	39 Months[4/] (12 Months - Progress Report)
165-2 - Rotational Crops (Field)	TEP	A,C	No		Reserved[5/]	
165-3 - Irrigated Crops	TEP	C,D	No		Yes	39 Months[4/] (12 Months - Progress Report)
165-4 - In Fish	TGAI or PAIRA	A,B,C,D,G	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	D,G	No		Yes	12 Months
Section 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		Reserved[6/]	
132-1 - Soil Dissipation	TEP	A	No		Reserved[6/]	
133-3 - Dermal Exposure	TEP	A,B	No		Reserved[6/]	
133-4 - Inhalation Exposure	TEP	A,B	No		Reserved[6/]	

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.440 - Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No		Reserved6/	
201-1 - Drift Field Evaluation	TEP	A,B	No		Reserved6/	
Section 158.75 - Other Exposure Data						
Mixer/Loader and Applicator Exposure Data			No		Reserved6/	

1/Due dates refer to number of months following receipt of this Registration Standard, unless otherwise indicated.
2/Data are reserved pending receipt and evaluation of vapor pressure data.
3/Due to results of preliminary data showing persistence of methoxychlor under aerobic conditions, the Agency is requiring a long-term soil field dissipation study. The short-term study is waived.
A separate study must be performed with a typical end-use product for each registered formulation category (D, WP, ED, and FC). The method of application must include both foliar application and seed treatment. An acceptable protocol is due 90 days from receipt of this Standard.
4/The first progress report is due 12 months from receipt of this Standard. Interim reports are due annually thereafter.
5/Reserved pending the results of the confined accumulation in rotational crops study.
6/No adequate data exist to fully evaluate the toxicity potential of methoxychlor. Therefore, this data requirement is reserved pending the results of acceptable toxicology studies.

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.340 Toxicology						
81-1 - Acute Oral - Rat	TGAI	A,B,D,E, G,I	No		Yes	9 Months
81-2 - Acute Dermal	TGAI	A,B,D,E, G,I	No		Yes	9 Months
81-3 - Acute Inhalation	TGAI	A,B,D,E, G,I	No		Yes	9 Months
81-4 - Eye Irritation	TGAI	A,B,D,E, G,I	No		Yes	9 Months
81-5 - Dermal Irritation	TGAI	A,B,D,E, G,I	No		Yes	9 Months
81-6 - Dermal Sensitization	TGAI	A,B,D,E, G,I	Partially	00062704	Yes2/	9 Months
81-7 - Acute Delayed Neurotoxicity	TGAI	N/A	No		No3/	
Subchronic Testing						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A,B,D,E G,I	No		No4/	
- Nonrodent	TGAI	A,B,D,E G,I	No		No4/	

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.340 Toxicology						
Subchronic Testing (cont'd)						
82-2 - 21-Day Dermal	TGAI	A,B,D,E, G,I	No		Yes	9 Months
82-3 - 90-Day Dermal	TGAI	A,B,D,E, G,I	No		No[5]	
82-4 - 90-Day Inhalation	TGAI	A,B,D,E, G,I	No		No[6]	
82-5 - 90-Day Neurotoxicity	TGAI	N/A				
Chronic Testing						
83-1 - Chronic Testing						
- Rodent	TGAI	A,B,D,E G,I	No		Yes	50 Months[7] (12 Months - Progress Report)
- Nonrodent	TGAI	A,B,D,E G,I	No		Yes	50 Months[7] (12 Months - Progress Report)

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Section 158.340 Toxicology						
Chronic Testing cont'd						
83-2 - Oncogenicity						
- Rat	TGAI	A,B,D,E, G,I	No		Yes	50 Months[7] (12 Months - Progress Report)
- Mouse	TGAI	A,B,D,E, G,I	No		Yes	50 Months[7] (12 Months - Progress Report)
83-3 - Teratogenicity						
- Rat	TGAI	A,B,D,E, G,I	No		Yes	15 Months
- Rabbit	TGAI	A,B,D,E, G,I	No		Yes[8]	15 Months
83-4 - Reproduction	TGAI	A,B,D,E, G,I	No		Yes	39 Months[7] (12 Months - Progress Report)
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A,B,D,E, G,I	No		Yes	9 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.340 Toxicology						
Mutagenicity Testing (cont'd)						
84-2 - Chromosome Aberration	TGAI	A,B,D,E, G,I	Yes	00028625 00132952 00133008	No	
84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B,D,E G,I	No		Yes	12 Months
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A,B,D,E G,I	No		Yes	24 Months (12 Months-Progress Report)
85-2 - Domestic Animal	Choice	I	No		Reserved2/	

Section 158.340 Toxicology - Footnotes

1/Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/A submitted study is available under MRID No. 000144386. This study only partially satisfies the requirement because test methodology was not provided. This registrant has the option of upgrading this study by providing a description of test methodology used, or submitting a new study. Within 90 days, the registrant must inform the Agency of the option chosen: 1) to provide the missing information to upgrade the study, or 2) to submit a new study. In either case the new study or the submission of additional data is due at the 9-month deadline.

Table A
Generic Data Requirements for Methoxychlor

Section 158.340 Toxicology - Footnotes (cont'd)

3/No acute delayed neurotoxicity study is available for methoxychlor. However, this test is required only for organophoshate compounds which inhibit cholinesterase. Methoxychlor is not an organophoshate, therefore, a study is not required.

4/These studies are not required since requirements for chronic rodent and nonrodent toxicity studies have been imposed by the Agency.

5/This study is not required because the registered use patterns of methoxychlor should not result in repeated dermal contact.

6/This study is not required because the registered use patterns of methoxychlor should not result in repeated inhalation exposure.

7/A progress report is due 12 months from receipt of this Standard. Interim reports are due annually thereafter.

8/The study submitted by Kinkaid (MRID 159929) in response to the 1984 Agency DCI was reviewed and determined to be unacceptable.

9/This requirement is reserved pending the results of other toxicity tests.

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.490 - Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Avian Single Dose Oral LD_{50}	TGAI	A,B,C,D, G,I	Yes	00160000	No	
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird	TGAI	A,B,C,D, G,I	Yes	00022923	No	
- Waterfowl	TGAI	A,B,C,D, G,	Yes	00229213	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A				
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	A,B,C,D, G	No		Yes	24 Months (12 Months - Progress Report)
- Waterfowl	TGAI	A,B,C,D, G	No		Yes	24 Months (12 Months - Progress Report)
71-5 - Simulated Field Testing for Birds and Mammals	TEP	A,B,C,D, G	No		Reserved2/	

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Section 158.490 - Wildlife and Aquatic Organisms						
Avian and Mammalian Testing (cont'd)						
71-5 - Actual Field Testing for Birds and Mammals	TEP	A,B,C,D,G	No		Reserved[2/]	
Aquatic Organism Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	A,B,C,D,G,I	Yes	40098001	No	
	TEP	A,B,C,D,G	Partially	40098001	Yes[3/]	9 Months
- Coldwater	TGAI	A,B,C,D,G,I	Yes	40098001	No	
	TEP	A,B,C,D,G	Partially	40098001, 00098800	Yes[3/]	9 Months
72-2 - Freshwater Invertebrate LC_{50}	TGAI	A,B,C,D,G,I	Yes	40098001	No	
	TEP	A,B,C,D,G	No		Yes	9 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Section 158.490 - Wildlife and Aquatic Organisms						
Aquatic Organism Testing cont'd)						
72-3 - Estuarine and Marine Organisms LC_{50}						
- Fish	TGAI	A,B,C,D, G	Yes	40228401	No	
	TEP	A,B,C,D, G	No		Yes	12 Months
- Shrimp	TGAI	A,B,C,D, G	Yes	40228401	No	
	TEP	A,B,C,D, G	No		Yes	12 Months
- Oyster	TGAI	A,B,C,D, G	Yes	40228401	No	
	TEP	A,B,C,D, G	No		Yes	12 Months
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Fish	TGAI	A,B,C,D, G,I[4]	No		Yes	15 Months
- Invertebrates	TGAI	A,B,C,D, G,I[4]	No		Yes	15 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Section 158.490 - Wildlife and Aquatic Organisms						
Aquatic Organism Testing cont'd)						
72-5 - Fish Life Cycle	TGAI	A,B,C,D,G	No		Reserved[5]	
72-6 - Aquatic Organism Accumulation (Fish)	TGAI	A,B,C,D,G	No		No[6]	
72-7 - Simulated or Actual Field Testing Aquatic Organisms -Aquatic Residue Monitoring or Mesocosm Study	TEP	A,B	No		Yes[7]	24 Months (Acceptable Protocol - 90 Days; Progress Report - 12 Months)
Section 158.540 Plant Protection Testing						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	C,D,G	No		Yes	9 Months
122-1 - Aquatic Plant Growth	TGAI	G	No		Yes[8]	9 Months

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Section 158.540 Plant Protection Testing (cont'd)						
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	C,D,G	No		Reserved[9/]	
123-1 - Vegetative Vigor	TGAI	C,D,G	No		Reserved[9/]	
123-2 - Aquatic Plant Growth	TGAI	C,D,G	No		Reserved[9/]	
TIER III						
124-1 - Terrestrial Field	TEP	C,D,G	No		Reserved[10/]	

1/Due dates refer to number of months following receipt of this Registration Standard, unless otherwise indicated.

2/The requirement is reserved pending the results of the required avian reproduction studies.

3/A typical emulsifiable concentrate formulation is required to support crop and aquatic uses. The requirement for a granular formulation (up to 50%) has been satisfied.

4/Required to support registration of the formulations applied to livestock, as the treated livestock may move into waterways.

5/This requirement is reserved pending the results of the fish early life stage and aquatic invertebrate life cycle tests.

6/Data are not required since the data required under Section 158.290 Environmental Fate (165-4) may be used to satisfy this requirement.

7/Aquatic residue monitoring studies are required to be conducted in aquatic environments for aquatic uses. As an alternative, a mesocosm study may be conducted. Monitoring studies are reserved for terrestrial uses depending upon results of better estimation of aquatic EECs through modeling. If aquatic residue monitoring studies show aquatic concentrations greater than 0.6 ppb, then mesocosm studies are required for the aquatic uses. Mesocosm testing for

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Section 158.540 Plant Protection Testing

terrestrial uses are reserved pending better refinement of aquatic EECs from modeling. Additionally, full field studies for other use patterns are reserved pending an evaluation of the results from the above studies and an analysis of their applicability to support other uses. For either mesocosm or full field studies, the study design must include appropriate techniques to determine acute mortality and effects on productivity and diversity of fish and aquatic invertebrates. Protocols for conducting residue monitoring, mesocosm, or full field studies must be submitted to the Agency. A Guidance Document is available from the Agency that outlines an acceptable approach to mesocosm studies. This document also provides relevant, although general, guidance for full field studies, which, if selected in place of mesocosm studies, must include multiple treated ponds and control ponds.

[8] Only the algae Selenastrum capricornutum is required initially. Based on results of this study, the testing of additional species may be required.

[9] This requirement is reserved pending results of Tier I studies.

[10] This requirement is reserved pending results of Tier II studies.

Table A
Generic Data Requirements for Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1/]
Section 158.590 Nontarget Insects						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Toxicity	TGAI	A,B,G	Yes	00036935	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,G	No		No[2/]	
141-4 - Honey Bee Subacute Feeding Study	Reserved[3/]					
141-5 - Field Testing for Pollinators	TEP	A,B,G	No		No[2/]	
Nontarget Insect Testing - Aquatic Insects						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[3/]					
142-2 - Aquatic Insect Life Cycle Study	Reserved[3/]					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[3/]					

Table A
Generic Data Requirements for Methoxychlor (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[1]
Section 158.590 Nontarget Insects						
Nontarget Insect Testing - Predators and Parasites						
143-1 thru 143-3	Reserved[3]					

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[1] Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

[2] As data from the acute contact test indicate low toxicity, no further testing is required.

[3] This requirement is reserved pending development of test methodology and/or decisions as to whether data should be required.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Methoxychlor

Data Requirement	Test Substance 1/	Use Patterns	Does EPA Have Data to Satisfy This Requirement?2/	Bibliographic Citation2/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission3/
Part 158, Subpart C - Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All			Yes4/	9 Months
61-2 - Description of Beginning Material and Manufacturing Process	MP	All			Yes5/	9 Months
61-3 - Discussion of Formation of Impurities	MP	All			Yes6/	9 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	All			Yes7/	12 Months
62-2 - Certification of Ingredient Limits	MP	All			Yes8/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All			Yes9/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All			Yes	9 Months
63-3 - Physical State	MP	All			Yes	9 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Methoxychlor

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data to Satisfy This Requirement?[2]	Bibliographic Citation[2]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission[3]
Part 158, Subpart C - Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-4 - Odor	MP				Yes	9 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP				Yes	9 Months
63-12 - pH	MP				Yes[10]	9 Months
63-14 - Oxidizing or Reducing Action	MP				Yes[11]	9 Months
63-15 - Flammability	MP				Yes[12]	9 Months
63-16 - Explodability	MP				Yes[13]	9 Months
63-17 - Storage Stability	MP				Yes	15 Months
63-18 - Viscosity	MP				Yes[14]	9 Months
63-19 - Miscibility	MP				Yes[15]	9 Months
63-20 - Corrosion Characteristics	MP				Yes	15 Months
Other Requirements						
64-1 - Submittal of Samples	MP	All			Reserved[16]	

Table B

Product-Specific Data Requirements for Manufacturing-Use Products Containing Methoxychlor

Part 158, Subpart C - Product Chemistry Footnotes

1/Formulation intermediates are also included in the category of manufacturing-use products (MPs).

2/Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each MP. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

3/Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

4/For each MP that consists of the technical grade of the active ingredient (TGAI) only or is produced by an integrated system, the following information must be provided: (i) the CAS-approved chemical name, CAS Registry Number, any common names, the nominal concentration, upper and lower certified limits in accordance with 40 CFR 158.175, and the purpose of each active and inert ingredient in the product; (ii) the molecular, structural and empirical formulae, and the molecular weight or weight range of each active ingredient in the product; (iii) the chemical name and nominal concentration of each impurity of toxicological significance associated with the active ingredient or present in any sample at a level equal to or greater than 0.1% by weight of the TGAI; and (iv) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that are not characterized. Impurities must be identified as such. For each MP that is produced from an EPA-registered product, the following information must be provided: (i) the chemical and common name of each active ingredient as listed on the source product, its nominal concentration in the product based upon the nominal concentration in the source product, and upper and lower certified limits in accordance with 158.175; (ii) the CAS-approved chemical name of each inert ingredient in the product, its CAS Registry Number, any common names, nominal concentration, purpose, and upper and lower certified limits in accordance with 158.175; and (iii) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized.

5/For each MP that is produced from an EPA-registered product, the following information must be provided: (i) the name and EPA Registration Number of the EPA-registered product; (ii) the brand name, trade name, or other commercial designation and information concerning the composition of each inert ingredient; (iii) a general characterization of the formulation or product process (e.g., batch or continuous); (iv) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (v) a description of the equipment used; (vi) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and (vii) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). For each MP that consists of the TGAI only or is produced by an integrated system, the following information must be provided in addition to that listed above: (i) the name and address of the producer if different from the registrant; (ii) the brand name, trade name or other commercial designation of each starting material, the name and address of its producer, and information concerning its composition; (iii) a flow chart of the chemical equations of each intended reaction occurring at each step of the process and of the entire process; and (iv) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

Table B

Product-Specific Data Requirements for Manufacturing-Use Products Containing Methoxychlor

Part 158, Subpart C - Product Chemistry Footnotes (cont'd)

6/For each MP product that consists of the TGAI only or is produced by an integrated system, a discussion regarding the following potential impurities must be provided: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, postproduction reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. For each MP that is produced from an EPA-registered product, a discussion must be provided for each impurity associated with the active ingredient which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the possible carryover of impurities present in the registered product which serves as the source of the active ingredient, the possible carryover of impurities present in the inert ingredients in the product, possible reactions occurring during the formulation of the product, postproduction reactions between any of the product's active ingredients and any other component of the product or its packaging, and possible contamination from packaging materials or production equipment.

7/For each MP produced by an integrated system, the registrant must provide preliminary analyses of five or more representative samples of each TGAI contained in the product to identify all impurities present at 0.1% or greater of the TGAI. Specific analysis for the potential impurities 1-chlor-1,2,2-tris(p-methoxyphenyl)ethylene (TACE), 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane (DDT), and its structurally similar compounds must be performed. If the product is produced by a batch process, at least five separate batches should be represented. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the TGAI must be provided. If the TGAI cannot be isolated, a statement of the composition of the practical equivalent of the TGAI must be submitted.

8/The registrant must propose upper and lower limits for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR 158.175(b)(2). Also, if the MP contains the TGAI only or is produced by an integrated system, upper limits must be proposed for each toxicologically significant impurity associated with the active ingredients and found to be present in any sample of the product (standard certified limits cannot be used for impurities). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Methoxychlor

Part 158, Subpart C - Product Chemistry Footnotes (cont'd)

The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85).

9/Analytical methods which are suitable for enforcement purposes must be provided for each active ingredient and each additional ingredient or impurity that is determined to be toxicologically significant. Suitability for enforcement purposes shall be determined from validation studies of method accuracy and precision submitted by the registrant.

10/Data on pH are required if the test substance is dispersible in water.

11/Data are required on oxidizing/reducing potential if product contains an oxidizing or reducing agent.

12/Data are required on flammability if the product contains combustible liquids.

13/Data are required if the product is potentially explosive.

14/Data on viscosity are required if the product is a liquid.

15/Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

16/If samples are needed, the Agency will request them.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Methoxychlor

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission1/
Section 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP2/	All	No		Yes	9 Months
81-2 - Acute Dermal	MP	All	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	MP	All	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	MP	All	No		Yes	9 Months
81-5 - Dermal Irritation						
- Rabbit	MP	All	No		Yes	9 Months
81-6 - Dermal Sensitization						
- Guinea Pig	MP	All	No		Yes	9 Months

1/Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/Formulation intermediates are also included in the category of MPs.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricul- tural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

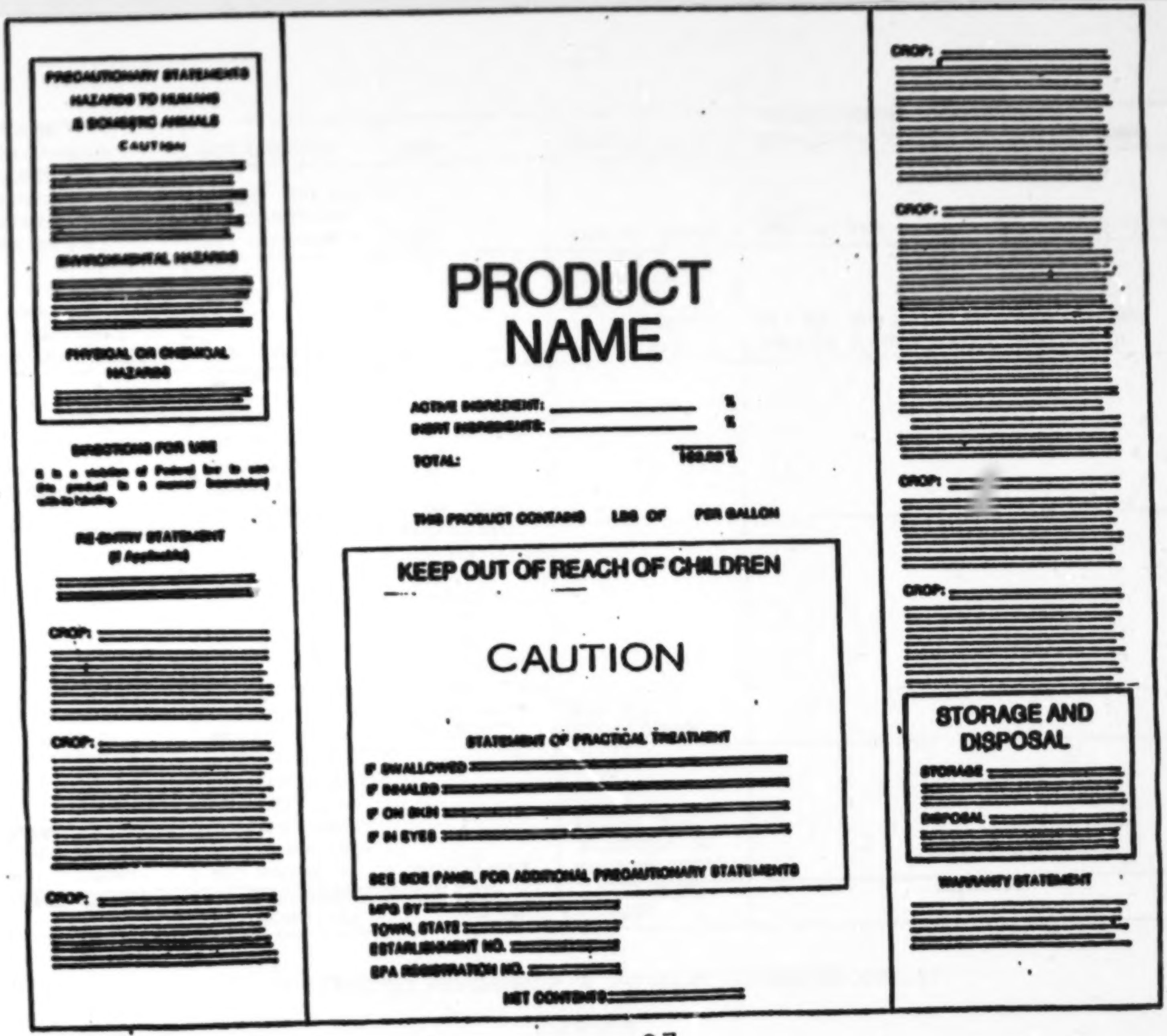
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . ." etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

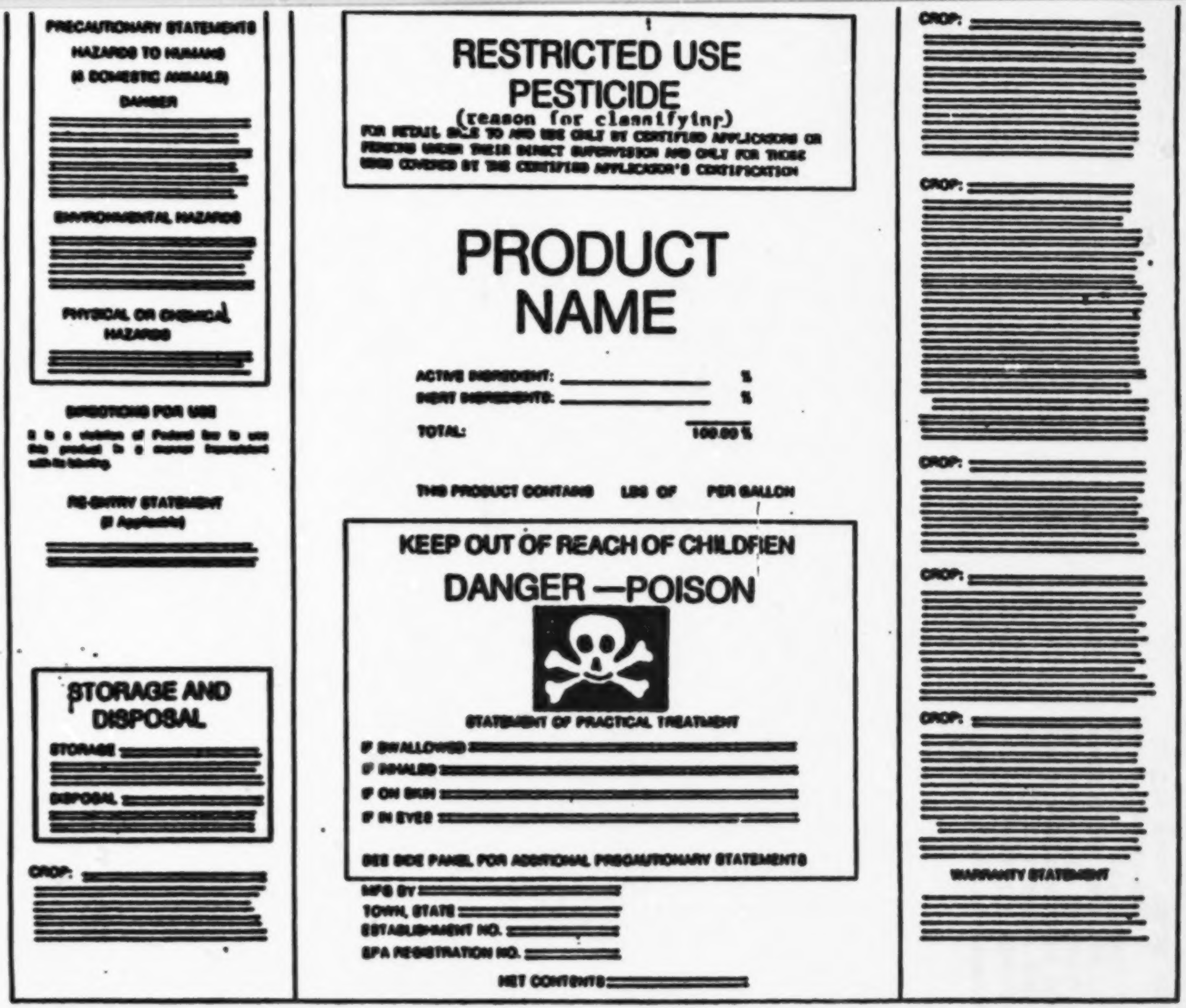
CROP:

CROP:

CROP:

STORAGE AND
DISPOSAL
STORAGE
DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: ____ %
INERT INGREDIENTS: ____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

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§ [illegible].10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handing. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978] tions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed direc-

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

IV. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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IV. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

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EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify __ALL__ four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA

US Environmental Protection Agency
Washington, DC 20460

Product Specific Data Report

Registration Standard for:

EPA Registration Number

Form Approved
OMB #2070-0057
Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data *(Attached)* *(Check below)*	
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

OMB Approval No. 2070-00
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:____________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ____________ concerning a requirement for submission of "generic" data on the active ingredient ____________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the produ contains the active ingredient solely as the result of the incorporation into the produc of another product which contains that active ingredient, which is registered under FIFR Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company nam registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated________________ on file with EPA is complete, current and accurate a contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________ and their registration number(s) is/are ____________________.

My firm will apply for an amendment to the registration prior to changing the sourc of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion this Statement is no longer true, or if my firm fails to comply with the undertakings ma in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for t product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit t required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data

Registrant's authorized representative:______________________________
(Signature

Dated: ____________________ ______________________________
(Typed)

EPA Form 8570-27